

Docket No.: W0571.70010US02
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thomas Tuschl et al.
Serial No.: 09/821,832
Confirmation No.: 6240
Filed: March 30, 2001
For: RNA SEQUENCE-SPECIFIC MEDIATORS OF RNA
INTERFERENCE
Examiner: L. V. Wollenberger
Art Unit: 1635

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Dated: October 22, 2009

Signature:  (Sharon R. Lloyd)

MAIL STOP PETITIONS
COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 22313-1450

**PETITION TO VACATE DECISION REVOKING
POWER OF ATTORNEY UNDER 37 C.F.R. § 1.36(a)**

Sir:

On September 3, 2009, the Office of Petitions ("the Office") granted Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften E.V.'s ("Max-Planck's") Petition to Revoke Power of Attorney Under 37 C.F.R. § 1.36(a) submitted on July 20, 2009 ("Max-Planck's Petition") in the above-referenced patent application, as well as various applications related by continuation or divisional status to the above application ("Tuschl I applications"). Whitehead Institute for Biomedical Research ("Whitehead"), Massachusetts Institute of Technology ("M.I.T."), and the University of Massachusetts ("UMass") (collectively "Petitioners"), each of whom was assigned an interest in the above-referenced patent application, respectfully submit this Petition to vacate the Office of Petitions' Decision Revoking Power of Attorney Under 37 C.F.R. § 1.36(a) in the Tuschl I applications ("Decision Revoking Power of Attorney").

When the Office granted Max-Planck's Petition, the Office did not have the benefit of considering the District Court's Memorandum and Order Denying Max-Planck's Motion for

Preliminary Injunction in *Max-Planck, et al. v. Whitehead, et al.*, Civ. Action No. 1:09-cv-11116-PBS (D. Mass.). (Exhibit A (District Court's Sept. 1, 2009 Memorandum and Order Denying Motion for Preliminary Injunction ("Order Denying PI Motion"))); *see also* copy attached to IDS filed on September 3, 2009.) In the Decision Revoking Power of Attorney, the Office explained that contractual agreements are not construed by the USPTO. Accordingly, the Office indicated that if a court decides this matter, that court decision should be filed. Decision Revoking Power of Attorney at 2. Petitioners thus submit the Order Denying PI Motion to the Office and request that the Office vacate its Decision Revoking Power of Attorney in light of the District Court's Order Denying PI Motion.¹

In the Order Denying PI Motion, Judge Saris, after considering the 2001 and 2003 Agreements,² held that Max-Planck did not demonstrate a likelihood of success on the merits on its breach of contract claim (as well as on its other claims). Max-Planck argued that Whitehead breached these agreements by refusing to follow Max-Planck's instructions regarding the prosecution of the Tuschl I patent applications. Order Denying PI Motion at 15. Judge Saris rejected Max-Planck's argument, and held specifically that "[t]he agreements do not give Max-Planck veto power over Whitehead's decisions in prosecuting the patent so long as the decisions are in good faith, as these appear to have been." Order Denying PI Motion at 16. Yet by granting Max-Planck's Petition, the USPTO may have effectively given Max-Planck this "veto power," thereby permitting Max-Planck to interfere with further prosecution of the Tuschl I

¹ In the alternative, to the extent the Office is not prepared to vacate its Decision Revoking Power of Attorney at this time, Petitioners request that the Decision Revoking Power of Attorney be stayed pending the resolution of the February 2010 trial in *Max-Planck, et al. v. Whitehead, et al.*, Civ. Action No. 1:09-cv-11116-PBS (D. Mass.). Responses are due in the upcoming months in many of the Tuschl I applications (*see, e.g.*, United States Patent Application Nos. 11/474919, 10/255568, 11/474932), and a potential consequence of the Decision Revoking Power of Attorney might ultimately be the forced abandonment of one or more of these applications. However, this risk will be removed if the Office stays its Decision until after the trial.

² The 2001 Joint Invention and Joint Marketing Agreement ("2001 Agreement") and the 2003 Joint Invention and Joint Marketing Agreement for RNAi Therapeutic Purposes ("2003 Agreement") are attached as Exhibits A and B to Petitioners' Petition in Response to Petition to Revoke Power of Attorney filed on July 31, 2009.

The District Court found that under the 2001 Agreement, Whitehead was responsible for managing the prosecution of the Tuschl I applications, that each party would have "reasonable opportunities to advise" Whitehead with respect to prosecution, and that each party would cooperate with Whitehead. Order Denying PI Motion at 9. Similarly, with respect to the 2003 Agreement, the District Court found that it provided that Whitehead would continue to be responsible for prosecuting the Tuschl I applications, that each party would have a "reasonable opportunity to comment and advise" on documents to be filed with the USPTO, and that Whitehead would "give good faith consideration" to such comments. Order Denying PI Motion at 10.

applications contrary to the provisions of the contracts and contrary to the District Court's interpretation thereof.

The District Court's reasoning in the Order Denying PI Motion is consistent with the conclusion that Max-Planck, as the assignee of only a partial interest in the Tuschl I applications (Thomas Tuschl, one of four inventors, assigned his interest in the applications jointly to Whitehead Institute and Max-Planck), has fallen well short of showing the "sufficient cause" required under 37 C.F.R. § 1.36(a) to revoke the power of attorney. *See* 37 C.F.R. § 1.36(a) ("[F]ewer than all of the assignees of the entire interest of the applicant" "may revoke the power of attorney only upon a showing of sufficient cause."); *see also* Manual Patent Examining Procedure ("MPEP") § 402.10 ("Papers revoking a power of attorney in an application . . . will not be accepted by the Office when signed by less than all of . . . owners of the application unless they are accompanied by a petition under 37 CFR [§] 1.36(a) . . . with a showing of sufficient cause."). Maintenance of the Max-Planck Petition under these circumstances would be contrary to both 37 C.F.R. § 1.36(a) and MPEP § 402.10 as well as to the District Court's holding that under the contracts Max-Planck does not have "veto power" over Whitehead's good faith decisions in prosecuting the Tuschl I applications. Thus, the Office of Petitions should vacate the Decision Revoking Power of Attorney.

Applicant believes no fee is due with this Petition. However, if a fee is due, please charge our Deposit Account No. 23/2825 under Docket No. W0571.70010US02 from which the undersigned is authorized to draw.

Dated: October 22, 2009

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Helen C. Lockhart".

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MAX-PLANCK-GESELLSCHAFT ZUR
FÖRDERUNG DER WISSENSCHAFTEN E.V.,
a corporation under the laws of
Germany; MAX-PLANCK-INNOVATION
GMBH, a corporation organized
under the laws of Germany; and
ALNYLAM PHARMACEUTICALS, INC., a
Delaware corporation,

Plaintiffs,

v.

WHITEHEAD INSTITUTE FOR BIOMEDICAL
RESEARCH, a Delaware corporation;
MASSACHUSETTS INSTITUTE OF
TECHNOLOGY, a Massachusetts
corporation; BOARD OF TRUSTEES OF
THE UNIVERSITY OF MASSACHUSETTS,
a Massachusetts corporation,

Defendants.

CIVIL ACTION NO.09-11116-PBS

MEMORANDUM AND ORDER

September 1, 2009

Saris, U.S.D.J.

I. INTRODUCTION

This dispute is about a process called "RNA interference" that can be used to "silence" genes and has potentially huge therapeutic value. Plaintiffs are Max-Planck Society for the Advancement of Science, a non-profit academic research

institution located in Germany¹ and Alnylam Pharmaceuticals, Inc., a Delaware corporation with a principal place of business in Cambridge, Massachusetts. They claim that the defendants Whitehead Institute for Biomedical Research ("Whitehead"), Massachusetts Institute of Technology ("MIT") and the Board of Trustees of the University of Massachusetts ("UMass") misappropriated an invention owned by Max-Planck.²

Among other things, plaintiffs allege that defendants have filed a patent application (the so-called Tuschl I patent application) with the United States Patent and Trademark Office ("USPTO") that contains plaintiffs' invention, which is itself the subject of another pending patent application (the so-called Tuschl II patent application). Plaintiffs seek a preliminary injunction pursuant to Fed. R. Civ. P. 65 enjoining defendants from prosecuting the Tuschl I patent applications and from paying the issuance fee in the event that the USPTO issues a notice of allowance.

After hearing and a review of the voluminous submissions,

¹ Its German name is Max-Planck-Gesellschaft zur Förderung der Wissenschaften E.V., and the technology-transfer arm is Max-Planck-Innovation GmbH.

² Plaintiffs assert breach of contract (Count 1); breach of the implied covenant of good faith and fair dealing (Count 2); breach of fiduciary duty (Count 3); waste (Count 4); interference with advantageous business relations (Count 5); unjust enrichment (Count 6); violation of Mass. Gen. Laws ch. 93A (Count 7); and negligence (Count 9); and also pursue a declaratory judgment (Count 8).

the Court **DENIES** the request for preliminary relief on the ground that plaintiffs have not shown a substantial likelihood of success on the merits.

II. BACKGROUND FACTS

The record contains evidence of the following facts, which are undisputed except where noted.

A. A Primer on RNA Interference

The parties provided a tutorial to explain the scientific background of RNA interference: genes in a cell are regions of DNA that hold codes for directing the synthesis of proteins. DNA is a double-stranded structure: two chains, oriented in opposite directions, which are bound together. When a gene is active, it is transcribed into a single stranded chain called messenger RNA ("mRNA"). The code contained in the mRNA is then translated into a protein. The chains of DNA and mRNA are composed of nucleotides. One end of these DNA and RNA strands is referred to as the 3-prime (3') end, and the other is referred to as the 5-prime (5') end.

RNA interference, RNAi, is a process in which a double-stranded RNA (dsRNA) is used to silence a specific gene in a cell by directing the destruction of mRNA produced by that gene before it is translated into a protein. The process works because when a dsRNA molecule is introduced into a normal cell, the cell will recognize it as abnormal or foreign to the cell because mRNA is

ordinarily composed of a single chain. As a result, the cell will direct the destruction of the dsRNA and all other RNA in the cell.

B. The First Patent Application - Tuschl I

Dr. Thomas Tuschl, Ph.D., is the first named inventor for the Tuschl I patent application. (Tuschl Aff. [Docket No. 51] ¶ 3.) He is currently an Associate Professor and the head of the Laboratory of RNA Molecular Biology at the Rockefeller University in New York. (Id. ¶ 1.) He is also the co-founder of plaintiff Alnylam. (Id.) His co-inventors on the Tuschl I patent are Philip Sharp of MIT, David Bartel of Whitehead, and Philip Zamore. (Id. ¶ 3.) Tuschl and Zamore were post-doctoral fellows at Whitehead. (Id. ¶ 10.) Their work involved a system for studying the process of RNAi in a test tube using the contents from inside certain cells of the fruit fly, *Drosophila*. (Id.) They discovered that introducing long dsRNA into their *Drosophila* system led to RNAi. (Id.) The inventors also determined that during the process, the dsRNA inserted into the cell was breaking into 21-23 nucleotide fragments. (Id. ¶ 12.) These fragments turned out to be capable of initiating RNAi. (Id.)

Because an article describing their work was scheduled to appear in the scientific journal Cell, on March 31, 2000,

Whitehead decided to file the first Tuschl I provisional³ patent application ("the '594 application") in the USPTO. (Id. ¶ 13.) The application was assigned to Whitehead, MIT, UMass and Max-Planck. (Granahan Aff. [Docket No. 36] ¶ 5.) It claimed "Isolated RNA of from about 21 to about 23 nucleotides which mediates RNA interference." (Haberny Aff. [Docket No. 15] Ex. A at 41.)

C. The Second Patent Application - Tuschl II

In late 1999, Dr. Zamore and Dr. Tuschl left Whitehead to become independent investigators in their own laboratories. (Tuschl Aff. ¶ 16.) Dr. Tuschl started his laboratory at Max-Planck and hired the two other Tuschl II inventors Sayda Elbashir and Winfried Lendeckel. (Id. ¶¶ 3, 16.) These inventors assert that they were the first to invent a synthetic dsRNA molecule with features that allow it to perform RNAi in mammalian cells -- as opposed to fruit flies. (Id. ¶ 38.) In plaintiffs' view, this was "groundbreaking" "because it opens the door for using RNAi technology as a human therapeutic agent." (Id.)

In the fall of 2000, the Tuschl II inventors discovered a

³ A provisional application is a type of application that does not need to contain all the details necessary to demonstrate patentability and does not mature into an issued patent unless a non-provisional application that includes those details is filed within 12 months. If a patent is later granted, it will relate back to the filing of the provisional application. See 35 U.S.C. § 111(b).

particular species of short RNA molecules, specifically, double-stranded molecules with a 1-3 nucleotide "overhang" on the 3' ends of the dsRNA strands. (Id. ¶ 24.) On October 25, 2000 they submitted the discovery to the scientific journal, Genes & Development, which published it in January 2001. (Id.) On December 1, 2000, Max-Planck filed a patent application ("the '325 application") in the European Patent Office ("EPO"). (Id. ¶ 25.) It claimed an "[i]solated double-stranded RNA molecule, wherein each RNA strand has a length from 19-23 nucleotides, wherein said RNA molecule is capable of target-specific nucleic acid modifications." (Granahan Aff. ¶ 11.) The '325 application is directed to the isolated, synthetic 21-23 nucleotide strands of RNA having at least one 3' overhang, which had been demonstrated to produce RNAi. (Tuschl Aff. ¶ 26.) Whitehead asserts that it did not know Max-Planck was filing this patent application with the EPO. (Mullins Aff. [Docket No. 34] ¶ 9.)

Shortly thereafter, the inventors learned that the synthetically produced, 21-nucleotide strands of RNA with 3' overhangs could cause RNAi in mammals. (Tuschl Aff. ¶ 27.) The data was subsequently published by the Tuschl II inventors in a May 2001 article in Nature entitled "Duplexes of 21-Nucleotide RNAs Mediate RNA Interference in Cultured Mammalian Cells." (Id. ¶ 28.)

Max-Planck, the sole assignee of the Tuschl II applications,

exclusively licensed its right in the Tuschl II applications to Alnylam for therapeutic purposes. (Erselius Aff. [Docket No. 26] ¶¶ 7, 14-16.)

D. Mammalian Data

In March 2001, the Tuschl I inventors faced the deadline to turn their provisional application into a non-provisional application. (Granahan Aff. ¶ 7.) Patricia Granahan, an attorney representing Whitehead, received experimental data regarding the use of isolated RNA segments of about 21 to 23 nucleotides to mediate RNAi in mammalian cells. (Id. ¶ 14.) She believed the data were generated by Tuschl subsequent to the filing of the Tuschl I provisional applications. (Id. ¶ 16.) Tuschl says he gave a manuscript of the journal article containing the mammalian data to Dr. Bartel, a Tuschl I inventor. (Tuschl Aff. ¶ 29.) When Bartel asked for permission to include the data in the Tuschl I patent application, Tuschl told him he did not have the authority to do so. (Id.) To get the authority to use the data in the Tuschl I patent application, Granahan discussed the inclusion of the mammalian data with Dr. Torsten Mammenbrauer, the representative of Max-Planck responsible for the patenting and commercialization of Tuschl I and II, and Dr. Wolfgang Weiss, a German Patent attorney representing Max-Planck. (Granahan Aff. ¶¶ 16-17.) Weiss agreed that she could include the mammalian data in the Tuschl I applications, and she received

a confirmatory letter. (Id. ¶ 17; Id. Ex. 8.) Weiss now asserts he did not fully understand the genesis of that data. (Weiss Aff. [Docket No. 12] ¶¶ 4-5.)

On March 30, 2001, the mammalian data was included in the Tuschl I applications as Example 5 and Figure 14. (Granahan Aff. ¶ 16.) This data contains a discussion of the 3' overhangs. (Tuschl Aff. ¶ 36.) Dr. Tuschl claims that the disclosures in the Tuschl I applications relating to the 3' overhangs, synthetic RNA, and mammalian cell activity are really the inventions of the Tuschl II inventors. (Id. ¶¶ 35-41.)

Simultaneously, on March 30, 2001, Weiss included the identical mammalian data in the specification of a provisional Tuschl II patent application (the '661 application). (Granahan Aff. ¶ 18.)

Granahan claims that she believed that the Tuschl I applications encompassed RNA molecules with 3' overhangs. (Id. ¶¶ 26-30.) Both sides were aware that one of the licensees was worried about an "overlap" in the patent applications. (Id. ¶ 22.) While Granahan suggested combining the applications, Weiss nixed the idea. (Id.) Instead, Whitehead and Max-Planck ultimately agreed to prosecute them separately, but claim priority to each other's applications. (Id.)

In March of 2001, Whitehead sent a copy of the Tuschl I applications to Max-Planck. (Id. ¶ 24.) Max-Planck did not

protest the inclusion of the mammalian data or any other information in the Tuschl I applications for two years. (Id.)

E. The Agreements

On September 19, 2001, Whitehead, MIT, UMass and Max-Planck entered into a "Joint Invention and Joint Marketing Agreement." (Id. ¶ 32; Erselius Aff. ¶¶ 9-10.) Under this agreement, Whitehead was responsible for managing the prosecution of the Tuschl I applications, and Max-Planck had responsibility to prosecute the Tuschl II applications. (Granahan Aff. ¶ 32; Erselius Aff. ¶¶ 9-10; Erselius Aff. Ex. B at 2.) The agreement also provided that all parties would have "reasonable opportunities to advise" Whitehead with respect to prosecution, and that each would cooperate with Whitehead. (Erselius Aff. Ex. B at 2.)

The 2001 agreement provided that the patents for Tuschl I and Tuschl II "shall be licensed together as a single package" for research purposes. (Id.) MIT was appointed as the exclusive licensing agent for the sale of licenses to non-European companies for research purposes, and Max-Planck was appointed as the exclusive agent to issue licenses to European companies for research purposes. (Id.) The agreement included a revenue sharing arrangement that divided the licensing revenue among the four institutions and four inventors. (Id. Ex. B at 3.) Licenses for therapeutic uses were not included. (Id.)

On July 30, 2003, three of the four parties (excluding UMass) executed a "Joint Invention and Joint Marketing Agreement for RNAi Therapeutic Purposes." (Id. ¶ 11.) This agreement specified that the Tuschl I and Tuschl II patents "shall be commercialized together as a single package" for therapeutic purposes, and it provided for a sharing of revenues among the three parties and four inventors. (Id. Ex. C at 5-6.) It also provided that Whitehead would continue to be responsible for prosecuting Tuschl I, and Max-Planck would continue to prosecute Tuschl II. (Id. Ex. C at 2-3.) Each party would have a "reasonable opportunity to comment and advise" on documents to be filed with the USPTO, and Whitehead and Max-Planck would "give good faith consideration" to such comments. (Id.)

UMass declined to join in the 2003 agreement and instead granted a license under its rights to Tuschl I for therapeutic purposes to Sirna Therapeutics, Inc., now a division of Merck & Co., and a license for limited purposes to a company called CytRx (now Rxi). (Id. ¶ 17; Mullins Aff. ¶ 21.) The other three owners of Tuschl I - Whitehead, MIT and Max-Planck - granted a license for therapeutic purposes to Alnylam in December 2002, and to another entity that was eventually acquired by Alnylam. (Erselius Aff. ¶¶ 14-16.) In exchange, Alnylam agreed to pay royalties to Max-Planck, which, pursuant to the 2003 agreement, is obligated to share this revenue among Max-Planck, Whitehead,

and MIT, which, in turn, must share some of it with the inventors. (Mullins Aff. ¶ 22.) Sirna is a competitor of Alnylam. (Erselius Aff. ¶ 17.)

F. Dissonance

UMass's decision not to join in the 2003 agreement and instead to grant a license to Sirna and CytRx created a situation where UMass's two therapeutic licensees have rights to the jointly-owned Tuschl I, and the other therapeutic licensee, Alnylam, has a license to both Tuschl I and the Max-Planck-owned Tuschl II. (Mullins Aff. ¶ 39.) Because of this, as Whitehead points out, the co-owners of Tuschl I have different incentives regarding prosecution of the Tuschl I applications than the co-owners of Tuschl II. (Id. ¶¶ 40-46.)

In late 2003, Max-Planck complained for the first time about the inclusion of the 3' overhangs and mammalian data in the Tuschl I applications. (Pls.' Letter of Aug. 3, 2009 [Docket No. 66] 2-3.) On May 3, 2004, John Pratt of the Whitehead Institute and Lita Nelsen, Director of the MIT Technology Licensing Office, sent a letter (the so-called Nelsen/Pratt letter) to UMass which stated:

We have been asked by Garching Innovation, the technology transfer of Max Planck Society (MPG) to confirm our understanding of the "overhang data" in the patent jointly owned by MPG, UMass, Whitehead and MIT.

The data relating to the overhangs originated

at MPG, who allowed us to use the data to strengthen the specification of the patent. The data was given to us contingent upon our not using it to claim nor provide support for claims to RNAi agents having 3' overhangs and their use. Claims containing the inventive subject matter of 3' overhangs were to be reserved for MPG's own patent. The attached letter from Garching sets that forth.

Given this requirement, we have never anticipated that we could/would draft and prosecute claims reciting 3' overhangs in our jointly owned patent application(s).

(Supplemental Haberny Aff. [Docket No. 50] Ex. A.)

The record is unclear as to whether this letter was sent to Max-Planck, but it was sent to Alnylam. (Pls.' Letter of Aug. 3, 2009, 2.) Joern Erselius, a managing director at Max-Planck, states that since 2003 he has "repeatedly" asked Whitehead to remove the information in the Tuschl II applications from the Tuschl I applications "to make clear to the USPTO that the Tuschl I and Tuschl II patent applications have distinct inventive subject matter and distinct inventors." (Erselius Aff. ¶ 19.)

On July 11, 2005, Whitehead filed an Information Disclosure Statement representing to the USPTO that the assignees of the Tuschl I applications did not rely on the 3' overhang data or the mammalian cell data. (Id. ¶ 20; Id. Ex. F.)

G. Patent Problems

In September 2007, the USPTO informed all owners of the Tuschl I and Tuschl II applications that it would not grant more than one patent on the same invention, and rejected both

applications on "obviousness-type double patenting" grounds.

(Id. ¶ 21.) Max-Planck continues to argue against the rejections at the USPTO.

In April 2008, a joint meeting was held among representatives of Max-Planck, MIT, Whitehead, and Alnylam to resolve the problem, to no avail. (Id. ¶ 22.) Max-Planck has continually requested that Whitehead remove the Tuschl II invention from the Tuschl I patent applications to overcome the USPTO double patenting rejections of the Tuschl II applications. (Id. ¶ 19.) Whitehead has refused to delete the information. (Id.)

In January 2009, Whitehead, MIT, and UMass demanded that Erselius sign a document that would permit a Tuschl I patent containing the contested information to issue. (Id. ¶ 23.) Erselius declined. (Id.) On May 29, 2009, defendants again demanded that Max-Planck sign a document to permit a Tuschl I patent containing the information to issue. (Id.) Max-Planck refused. (Id.)

On June 18, 2009, Whitehead filed documents with the USPTO arguing that (1) the USPTO should allow one of the Tuschl I patent applications because it was filed earlier than the Tuschl II patent applications, and (2) any rejections based on double patenting should not be made to the Tuschl I patent applications. (Lockhart Aff. [Docket No. 31] Ex. 2 at 8-13.) Whitehead did not

consult with Max-Planck before submitting these arguments, although it did send a draft of the submission beforehand. (Id. ¶¶ 19-21.)

On June 26, 2009, Max-Planck filed this suit. The once-friendly inventors are now warring. There is stalemate.

III. DISCUSSION

A. Standard of Review

It is well-settled that, when considering a motion for a preliminary injunction, a district court must weigh four factors: (1) the plaintiff's likelihood of success on the merits; (2) the potential for irreparable harm in the absence of an injunction; (3) whether issuing an injunction will burden the defendants less than denying an injunction would burden the plaintiffs (i.e., a balancing of the equities); and (4) the effect, if any, on the public interest. United States v. Weikert, 504 F.3d 1, 5 (1st Cir. 2007). A preliminary injunction is a "potent weapon." Charlesbank Equity Fund II v. Blinds To Go, Inc., 370 F.3d 151, 163 (1st Cir. 2004). Therefore, the party seeking the injunction bears the burden of demonstrating each factor. See Granny Goose Foods, Inc. v. Bhd. of Teamsters & Auto Truck Drivers Local No. 70, 415 U.S. 423, 441 (1974).

The first two factors - likelihood of success on the merits and irreparable harm - are threshold issues; a plaintiff who is unable to demonstrate either must fail in his quest for

preliminary injunctive relief. See Weikert, 504 F.3d at 5 ("[I]f the moving party cannot demonstrate that he is likely to succeed in his quest, the remaining factors become matters of idle curiosity.") (quoting New Comm Wireless Servs., Inc. v. SprintCom, Inc., 287 F.3d 1, 9 (1st Cir. 2002)); Ross-Simons of Warwick, Inc. v. Baccarat, Inc., 217 F.3d 8, 13 (1st Cir. 2000) ("Irreparable harm is an essential prerequisite for a grant of injunctive relief.").

B. Likelihood of Success

Plaintiffs argue that they have a likelihood of success on their common law and statutory claims based on defendants' "deliberate" and "flagrant" efforts to misappropriate Max-Planck's intellectual property and their misrepresentation of the ownership of the Tuschl II inventions to the USPTO. Among other things, Max-Planck argues that Whitehead breached their agreements by refusing its request to exclude the Tuschl II information from the Tuschl I applications.

Max-Planck's opening thrust is that defendants, who dealt only with the *Drosophila* fruit fly, misappropriated its 3' overhangs and mammalian data in the Tuschl I applications. This argument will not fly, as Max-Planck's lawyer, Mr. Weiss, unconditionally authorized Whitehead in writing to include the information and data. While Mr. Weiss suggests that Whitehead's counsel did not act in good faith because she did not fully

explain the origins of the data, there is no evidence of fraudulent misrepresentation or any bad faith. Moreover, even if there had been a misunderstanding by Mr. Weiss as to who generated the data, which is unlikely, the full patent application with the disputed information was sent to Max-Planck before it was filed, and Max-Planck did not protest the inclusion of the information for two years.

As for refusing Max-Planck's requests, Whitehead points out that it did give good-faith consideration to Max-Planck's "comments and advice" in prosecuting the Tuschl I patent, but is not required by the agreements to follow Max-Planck's instructions to the detriment of Whitehead and the other assignees. The agreements do not give Max-Planck veto power over Whitehead's decisions in prosecuting the patent so long as the decisions are in good faith, as these appear to have been. See Eigerman v. Putnam Invs., Inc., 877 N.E. 2d 1258, 1264 (Mass. 2007) ("The covenant does not supply terms that the parties were free to negotiate, but did not").

A harder question involves the claims of breach of fiduciary duty and the covenant of good faith and fair dealing. This dispute began to simmer in late 2003, when plaintiffs first complained about the 3' overhangs and mammalian data in the Tuschl I applications. In the "Nelsen/Pratt letter," MIT and Whitehead stated that the "overhang data" was given to them "to

strengthen the specification of the patent" and was "contingent upon our not using it to claim nor provide support for claims to RNAi agents having 3' overhangs and their use." Max-Planck argues that Whitehead has violated this specific promise by claiming ownership of the 3' overhangs before the USPTO. The evidence in the record is muddled on this point. In its most recent filings before the USPTO, Whitehead did not make a claim of ownership of the 3' overhangs. (Erselius Aff. Ex. I at 11 ("The claims of the instant invention are silent as to the occurrence of a 3' overhang").) In this litigation, Whitehead has reiterated that "the Tuschl I inventors have not claimed 3' overhangs here." (Def. Whitehead's Sur-reply [Docket No. 58] 8.) Despite this disclaimer, in letters recently filed in this Court, Whitehead has appeared to backpedal, asserting that they only agreed not to assert "species" claims to the 3' overhangs. (Def. Whitehead's Letter of Aug. 6, 2009 [Docket No. 74] 4 ("Whitehead did agree that Tuschl I applications would not include claims that expressly recited 3' overhangs as a species of the claimed genus."); Id. at 5 (contending that "Whitehead never committed that it would not prosecute genus claims that encompass embodiments with 3' overhangs").) MIT similarly writes:

MIT agreed only that it would not use the data relating to the overhangs to support seeking *species* claims to the 3' overhang species in the Tuschl I application and, to date, Plaintiffs have never complained that such claims have been pursued.

(Def. MIT's Letter of Aug. 5, 2009 [Docket No. 71] 4.) The Nelsen/Pratt letter, though, draws no distinction between genus and species claims. Rather, it plainly states, "claims containing the inventive subject matter of 3' overhangs were to be reserved for [Max-Planck's] own patent." (Supplemental Haberny Aff. Ex. A.)

Whitehead, MIT, and Max-Planck appear to agree that Tuschl II is a "species" claim that is allowable after the issuance of the "genus claim" in the Tuschl I provisional application. This is a plausible argument because the PTO's rules state that a species claim can be patentably distinct from an earlier genus claim. See 37 C.F.R. § 1.146. Still, Max-Planck voices the concern that the overhangs and mammalian data will be used to support the broadly worded Claim One in the Tuschl I application. This concern is valid because a later species claim may constitute double-patenting and would not be patentable if it is obvious in light of the claims of the earlier genus, see In Re Kaplan, 789 F.2d 1574 (Fed. Cir. 1986), and the patent examiner here rejected the Tuschl II applications on obviousness-type double patenting grounds.

Recently, in Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 518 F.3d 1353 (Fed. Cir. 2008), the Federal Circuit clarified the law in this area, stating "obviousness-type double patenting analysis" involves a two step process: (1) the "court construes

the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences;" and (2) the court "determines whether those differences render the claims patentably distinct." Id. at 1363. A court may "examine[] the specifications of both patents to ascertain any overlap in the claim scope for the double patenting comparison." Geneva Pharm., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1385 (Fed. Cir. 2003). A later species claim may not be patentable if practicing the prior claim inherently produces the subject matter of the later claim. See, e.g., Eli Lilly & Co., v. Barr Labs., Inc., 251 F.3d 955, 968-72 (Fed. Cir. 2001). No doubt this is a complicated, arcane area of patent law fraught with land mines. Both sides have had experienced patent counsel, and realized that both applications have broad initial claims which might overlap in ways troubling to the USPTO. Both sides knowingly took the risk based on genus/species law and rolled the dice, rather than combining the patents, the safer bet.

Furthermore, the dispute concerning the Tuschl I applications has been percolating for years. Max-Planck knew that the Tuschl I applications contained the relevant information as early as 2001, and by its own admission it began to complain about this fact only late in 2003. It knew UMass continued to disagree with Max-Planck's position in July 2004. (Def. Whitehead's Letter of Aug. 6, 2009, Ex. 3.) By 2007, it knew

that the USPTO had rejected both applications on double patenting grounds.

Trying to swat away the lapse in years, plaintiffs state without persuasive facts that after the USPTO indicated for the first time in 2007 that it would reject both applications on obviousness-type double patenting grounds, they "expected that Defendants would agree to withdraw the Tuschl II material from the Tuschl I applications without the need for judicial assistance." (Pls.' Letter of Aug. 3, 2009 [Docket No. 66] 5.) They vaguely claim that the April 2008 meeting gave them reason to "hope" for a resolution. (Id.) Still plaintiffs waited over a year after that meeting to file this lawsuit to require Whitehead to delete the information in an application pending before the USPTO. This highly complex suit was filed in state court, which has little or no patent expertise, just before the July Fourth weekend, seeking an emergency injunction. A party cannot delay the initiation of litigation and then use an "emergency" created by its own decisions concerning timing to support a motion for preliminary injunction. See Baer v. Nat'l Bd. of Med. Exam's, 392 F. Supp. 2d 42, 48-49 (D. Mass. 2005).

More substantively, defendants argue that plaintiffs' claims are barred by the doctrine of laches because of this delay. See K-Mart Corp. v. Oriental Plaza, Inc., 875 F.2d 907, 911 (1st Cir. 1989). Whitehead contends that requiring it to amend its

application by deleting the information at such a late date in the USPTO proceedings might prejudice Whitehead, which has the contractual authority to prosecute the Tuschl I patent. It states that it needs this information because it is necessary to comply with the best mode requirements of 35 U.S.C. § 112. (See Burchfiel Aff. [Docket No. 35] ¶¶ 14-28.) This argument is somewhat difficult to credit fully as Whitehead stated in its July 11, 2005 Information Disclosure Statement that it did not rely on the overhangs or the mammalian data to support its claims and it has eschewed claims to inventorship of the '3 overhangs. Nevertheless, Whitehead has a persuasive argument that requiring it to amend the application after so many years of patent prosecution would be prejudicial.

The Court thus **DENIES** plaintiffs' motion for a preliminary injunction. Plaintiffs have not demonstrated a likelihood of success on their core claim that defendants misappropriated their invention by putting the overhang and mammalian data in the Tuschl I applications and refusing to take it out because plaintiffs specifically authorized defendants to do so. Likewise, plaintiffs have not demonstrated a likelihood of success on their claims that Whitehead breached its common law or statutory duties by filing a claim which may include the 3' overhangs because both sides knowingly took the risk in a complex area of law of filing separate overlapping patents and because,

under the doctrine of laches, plaintiffs have likely unduly delayed pressing their claims. In light of this resolution, the Court does not address the defendants' numerous other arguments.

ORDER

The motion for preliminary injunction [Docket No. 9] is
DENIED.

S/PATTI B. SARIS
United States District Judge